Rejection of Claims 1-17 Under 35 U.S.C. 112

Claims 1-17 stand rejected under 35 U.S.C. 112 on the basis that language in claims 1, 12 and 14 renders those claims, and the claims dependent therefrom, indefinite.

Claims 1 and 12 have been amended in ways that address the stated ground of rejection. The language objected to in claim 14, however, has been left unchanged. It is the Applicant's contention that the phrases "major proportion" and "minor proportion", when read in view of the specification, are sufficiently definite to satisfy the requirements of 35 U.S.C. 112. In particular, an explanation of these terms is found in the specification at page 12, lines 14-27, where it is explained that a minor proportion of hydrophilic polymers in the coating will lead to an extended elution time of the therapeutic agent in the polymeric coating. It is respectfully suggested that one of ordinary skill in the art could, in view of this disclosure and the specific examples provided by the applicant (see Examples 6 and 7), discern a suitable minor proportion of hydrophilic polymer or co-polymer in the coating, without undue experimentation, even if this proportion varied depending on the polymers or co-polymers used in the coating and the therapeutic agent therein. Accordingly, the Applicant respectfully traverses the stated rejection of claim 14 under 35 U.S.C. 112.

Rejection of Claims 1, 2, 7-10 and 12-17 Under 35 U.S.C. 112

Claims 1, 2, 7-10 and 12-17 stand rejected under 35 U.S.C. 112 as being anticipated by U.S. Patent 5,525,348 to Whitbourne et al (hereinafter referred to as "Whitbourne '348").

As filed, claim 1 was distinguishable from Whitbourne '348 because the claims defined a device having a medicated polymeric coating on a scaffold member. A scaffold is a particular type of substrate defined in the specification at page 7, lines 14-25 as one configured to permit the polymer coating not only to cover its surface but also to permit the polymer coating to bridge from one part of the substrate surface to another. Nowhere does Whitbourne '348 teach or suggest the use of such a substrate in a medically-coated device. Therefore, claim 1 and the claims dependent therefrom are clearly distinguishable from Whitbourne '348. Accordingly, the stated ground of rejection of claim 1 is respectfully traversed.

Claims 6 and 7 each provide an additional distinction over Whitbourne '348 by stating that the therapeutic agent is present in therapeutic quantities, claim 6 stating the quantity in terms of loading in the coating and claim 7 defining the loading in functional terms relating to dispersion of the agent to tissue in a one-centimeter region from the device within which the therapeutically effective amount is delivered. Claim 12 is likewise distinguishable from Whitbourne '348 because it specifies that the polymeric coating contains a sufficient loading of the therapeutic agent to provide a therapeutic quantity of the agent to tissue extending at least one centimeter from the device in the patient's body. In contrast (as noted by the Applicant in the specification at page 11, line 24 through page 12, line 14), Whitbourne '348 discloses a medicated polymer coating with a loading of medication suitable only for "prophylactic" use, i.e., the prevention of infection or inflammation at the surface of the device. The incorporation of therapeutic quantities of therapeutic agents (as recited in claims 6, 7 and 12) is not disclosed or suggested by Whitbourne '348. As stated in the subject application at page 11, lines 26-28, this aspect of the invention results from the discovery that therapeutic quantities of therapeutic agents could be loaded in a hybrid polymeric coating comprising a major portion of hydrophilic polymeric materials and a minor portion of hydrophobic polymeric materials, and that the ability of a polymeric coating to contain and suitably release such quantities of therapeutic agent was not known or suggested in the prior art. Since the prior art devices described in Whitbourne '348 can only contain prophylactic quantities of medicine (i.e., amounts sufficient to prevent surface pathologies) the quantities of therapeutic agent recited in claims 6, 7 and 12 provide clearly patentable distinctions relative to the applied reference. Accordingly, the stated ground of rejection is respectfully traversed.

Rejection of Claims 1-10 and 12-17 Under 35 U.S.C. 103

Claims 1-10 and 12-17 stand rejected under 35 U.S.C. 103 as being obvious in view of Whitbourne '348, the Examiner stating that the mere difference in doses of active ingredients is obvious.

Claims 1-10 are all patentably distinguishable from Whitbourne '348 because base claim 1 defines a device in which the medicated polymeric coating is on a scaffold member, as discussed above in addressing the rejection under 35 U.S.C. 102. Since Whitbourne '348 nowhere discloses or suggests the use of a scaffold member as

a substrate for a medicated polymeric coating, claims 1-11 are all patentably distinguishable from Whitbourne '348. In addition, only the Applicant has taught how to prepare the polymer coating so that it can adequately carry and suitably release therapeutic agent therein in the quantity set forth in claims 6, 7 and 12, i.e., through the use of a hybrid polymer of hydrophilic and hydrophobic polymers or co-polymers, in which the hydrophilic polymers or co-polymers constitute a major proportion of the polymeric coating relative to the hydrophobic polymeric materials (see the application at page 12, lines 14-26). Nowhere does Whitbourne '348 disclose this outcome of using such a proportion of hydrophilic and hydrophobic polymeric materials. Accordingly, the polymeric coating of the claimed invention provides still another patentable distinction relative to the prior art.

Rejection of Claims 1-17 Under U.S.C. 103

Claims 1-17 stand rejected under 35 U.S.C. 103 as being unpatentable over Whitbourne '348 in view of U.S. Patent 6,306,176 to Whitbourne (hereinafter referred to as "Whitbourne '176"). The Examiner asserts that all of the pertinent aspects of the invention are shown by Whitbourne '348 except the combination of acrylate polymer and PVP/VA co-polymer in a weight ratio in the range of 1.5:1 to 7:1. Whitbourne '176 is cited for his disclosure of acrylic polymers and co-polymers, including PVP/P/VA polymers, the Examiner asserting that it would be obvious to employ polymers disclosed in Whitbourne '176 in the device described in Whitbourne '348.

Nowhere does Whitbourne '176 disclose or suggest an implantable medical device comprising a medicated polymer coating on a scaffold as defined in claim 1 and described in the subject patent application. Accordingly, even when Whitbourne '348 and Whitbourne '176 are viewed together, they do not render obvious either of claim 1 or 12 or the claims dependent therefrom.

Furthermore, like Whitbourne '348, Whitbourne '176 discloses coated medical devices containing agents in prophylactic amounts to prevent pathologies at the surface of the device, not in therapeutic amounts. Thus, the loading of medicated material in the polymeric coating of the claimed devices provides a further patentable distinction over the applied references, for the reasons set forth above to address the rejection of the claims under 35 U.S.C. 102. Even though Whitbourne '176 discloses the polymeric materials not shown by Whitbourne '348, neither of these references teach the

relative hydrophilic-hydrophobic proportions necessary to permit the desired loading of therapeutic agent in the coating. Therefore, the combination of Whitbourne '348 and Whitbourne '176 fails to render obvious the inventions of claims 6, 7 or 12, or the claims dependent therefrom.

For the foregoing reasons, the applied references fail to render any of claims 1-17 obvious. Accordingly, the stated ground of rejection is respectfully traversed.

New Claims 18-22

New claims 18-22 are allowable at least because they depend from base claims that are allowable, for reasons set forth above. These claims, instead of referring to delivery of therapeutic quantities of the therapeutic agent for "an extended period of time", a phrase which was objected to by the Examiner, refer to a period of time of at least two weeks. Support for this limitation is found in the application at page 12, lines 17-20.

Each of the stated grounds of rejection have been addressed or traversed. Re-examination and reconsideration of the application is respectfully requested.

Respectfully submitted,

Frederick A. Spaeth
Registration No. 33,793
Attorney for Applicant

Libert & Associates
3 Mill Pond Lane
P.O. Box 538
Simsbury, CT 06070-0538

Telephone: (860) 651-9321
Facsimile: (860) 651-5735

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AMENDED CLAIMS, SHOWING THE AMENDMENTS MADE

Added material is underlined, deleted material is [bracketed].

1. (once amended) A medicated device comprising:

a scaffold member suitable for implantation in a patient's body [at a tumor or other lesion site]; and

a polymeric coating [("med coat")] on the scaffold member[; and] , the polymeric coating containing at least one therapeutic agent [in the med coat at a loading sufficient to provide therapeutic quantities of the therapeutic agent to the site for an extended period of time].

2. (once amended) The device of claim 1 comprising an anti-cancer therapeutic agent in the polymeric coating [med coat].

3. (once amended) The device of claim 1 comprising at least 5 micrograms (μg) of at least one therapeutic agent per square centimeter of the polymeric coating [med coat].

4. (once amended) The device of claim 3 comprising at least 50 μg of at least one therapeutic agent per square centimeter of the polymeric coating [med coat].

5. (once amended) The device of claim 4 comprising at least 100 μg of at least one therapeutic agent per square centimeter of the polymeric coating [med coat].

6. (once amended) The device of claim 5 comprising at least 500 μg of at least one therapeutic agent per square centimeter of the polymeric coating, wherein the polymeric coating comprises a major proportion of one or more hydrophilic polymer materials and a minor portion of one or more hydrophobic polymer materials [med coat].

7. (once amended) The device of claim 1 comprising sufficient quantity of a therapeutic agent to deliver therapeutically effective quantity of a therapeutic agent into tissue in a region of at least one centimeter from the device, wherein the polymeric coating comprises a major proportion of one or more hydrophilic polymer materials and a minor portion of one or more hydrophobic polymer materials.

9. (once amended) The device of any one of claims 1-5 wherein the [med coat] polymeric coating comprises a hybrid polymeric coating comprising a hydrophilic polymer component and a hydrophobic polymer component.

12. (once amended) A medicated device comprising:

a substrate suitable for implantation in a patient's body; and

a polymeric coating [("med coat")] on the substrate [scaffold member; and], the polymeric coating comprising at least one therapeutic agent [in the med coat] at a loading sufficient to provide therapeutic quantities of [the] therapeutic agent to the patient's tissue in a region in the body extending at least one centimeter from the device, wherein the polymeric coating comprises a major proportion of one or more hydrophilic polymer materials and a minor portion of one or more hydrophobic polymer materials.

13. (once amended) The device of claim 12 comprising [sufficient quantity of a] a loading of the at least one therapeutic agent sufficient to deliver a therapeutically effective quantity of [a] therapeutic agent into tissue in a region of at least two centimeters from the device.

14. (once amended) The device of claim 12 or claim 13 [comprising a hybrid] wherein the polymeric coating [comprising] comprises a major proportion of one or more hydrophilic polymer materials and a minor proportion of one or more cellulose ester polymers.